Exhibit 11

108TH CONGRESS *1st Session* | HOUSE OF REPRESENTATIVES | REPORT 108–391

MEDICARE PRESCRIPTION DRUG, IMPROVEMENT, AND MODERNIZATION ACT OF 2003

CONFERENCE REPORT

TO ACCOMPANY

H.R. 1

NOVEMBER 21 (legislative day, NOVEMBER 20), 2003—Ordered to be printed

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Mr. THOMAS, from the committee of conference, submitted the following

CONFERENCE REPORT

[To accompany H.R. 1]

The committee of conference on the disagreeing votes of the two Houses on the amendments of the Senate to the bill (H.R. 1), to amend title XVIII of the Social Security Act to provide for a voluntary program for prescription drug coverage under the Medicare Program, to modernize the Medicare Program, to amend the Internal Revenue Code of 1986 to allow a deduction to individuals for amounts contributed to health savings security accounts and health savings accounts, to provide for the disposition of unused health benefits in cafeteria plans and flexible spending arrangements, and for other purposes, having met, after full and free conference, have agreed to recommend and do recommend to their respective Houses as follows:

That the House recede from its disagreement to the amendment of the Senate to the text of the bill and agree to the same with an amendment as follows:

In lieu of the matter proposed to be inserted by the Senate amendment, insert the following.

SECTION 1. SHORT TITLE; AMENDMENTS TO SOCIAL SECURITY ACT; REFERENCES TO BIPA AND SECRETARY; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the "Medicare Prescription Drug, Improvement, and Modernization Act of 2003".

(b) AMENDMENTS TO SOCIAL SECURITY ACT.—Except as otherwise specifically provided, whenever in division A of this Act an amendment is expressed in terms of an amendment to or repeal of a section or other provision, the reference shall be considered to be made to that section or other provision of the Social Security Act.

(c) BIPA; SECRETARY.—In this Act:

Assessment of the price controls and other such practices used by the countries identified.

Estimate of additional costs to U.S. consumers because of such price controls and other such practices, and the extent to which additional costs would be reduced for U.S. consumers if price controls and other such practices are reduced or eliminated.

Estimate of the impact such price controls, intellectual property laws, and other such measures have on fair pricing, innovation, generic competition, and research and development in the United States and each country identified.

Not later than 9 months after the date of enactment of this Act, the report shall be submitted to the Committees on Finance, the Judiciary, and Health, Education, Labor, and Pensions of the Senate, and the Committees on Ways and Means, the Judiciary, and Energy and Commerce of the House of Representatives.

In addition, the United States Trade Representative, the Secretary of Commerce, and the Secretary of Health and Human Services shall analyze whether bilateral or multilateral trade or other negotiations present an opportunity to address these price controls and other such practices and shall develop a strategy to address such issues in appropriate negotiations. In so doing, these agencies shall bear in mind the negotiating objective set forth in the Bipartisan Trade Promotion Authority Act of 2002 to achieve the elimination of government measures such as price controls and reference pricing which deny full market access for United States products. In so doing, the agencies shall provide periodic and timely briefings for the Committees of the House and Senate listed above, with an interim briefing no later than 90 days after enactment to address negotiations to establish a U.S.-Australia Free Trade Agreement and, as appropriate, other current negotiations.

Provisions Related to Hatch-Waxman Law

AMENDMENTS AND SUPPLEMENTS

In including this provision, Congress does not intend this provision to alter current U.S. Food and Drug Administration's ("FDA") practice regarding acceptance of supplements to approved new drug applications ("NDAs"), or amendments and supplements to pending and approved abbreviated new drug applications ("ANDAs"). Instead, Congress intends this provision to reflect the FDA's current practice regarding those changes and variations to both innovator and generic drugs that may be approved under amendments and supplements to previously filed NDAs and ANDAs, and expects the Agency to maintain its current policy in designating "listed drugs." The conferees intend that FDA continue to use its existing scientific discretion to determine whether different polymorphs present safety, effectiveness, or bioavailability differences and therefore should be considered the same or different active ingredients.

The single 30-month stay provisions are a centerpiece of this legislation, allowing lower-priced generic products to enter the market more quickly. As a result, this provision must not be construed as requiring an ANDA applicant to file a new application where, before its enactment, the applicant would have been allowed to file

an amendment or supplement to an existing application. Such a construction would run directly contrary to Congress' intent.

DECLARATORY JUDGMENTS

The conferees expect that courts will find jurisdiction, where appropriate, to prevent an improper effort to delay infringement litigation between generic drug manufacturers and pioneer drug companies. The conferees expect courts to apply the "reasonable apprehension" test in a manner that provides generic drug manufacturers appropriate access to declaratory judgment relief to the extent required by Article III.

Through the modifications in this Act, the conferees do not intend for the courts to modify their application of the requirements under Article III that a declaratory judgment plaintiff must, to the extent required by the Constitution, demonstrate a "reasonable apprehension" of suit to establish jurisdiction. See, e.g., *Fina Oil and Chemical Co.* v. *Ewen, 123 F.3d 1466, 1471* (Fed. Cir. 1997). The conferees expect the courts to examine as part of their analysis the particular policies served by the Hatch-Waxman Act.

In determining whether a reasonable apprehension of suit exists where an ANDA has been filed with a paragraph IV certification and the patentee has not brought an infringement suit within the 45 days, the conferees expect courts to examine these specific factors as part of the totality of the circumstances. See, e.g., *Vanguard Research, Inc.* v. *Peat, Inc., 304 F.3d 1249, 1254* (Fed. Cir. 2002). In any given case, the conferees expect a court may or may not find a reasonable apprehension of suit where these two specific factors are present.

Counterclaims

Section 1101 of the Conference agreement prohibits the recovery of damages resulting from a successful counterclaim in a paragraph IV patent suit by an ANDA applicant seeking removal of a patent listed in the Orange Book. It is not the intent of Congress to prohibit the recovery by a counterclaimant in a paragraph IV suit of anti-trust or any other damages as a result of the improper listing of a patent in the Orange Book. The language found in this section simply means that in the absence of any other cause of action, a ruling in favor of the counterclaimant resulting in the removal of the patent does not entitle the counterclaimant to recover damages.

TITLE XII—HEALTH SAVINGS INCENTIVES

Health Savings Accounts and Health Savings Security Accounts (sec. 1202 of the House bill and new sec. 223 of the Code)

Present Law

OVERVIEW

Present law contains a number of provisions dealing with the Federal tax treatment of health expenses and health insurance coverage.